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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,174	03/15/2005	Henryk Struszczyk	7007USO1	6038
23492	7590	10/13/2005		
ROBERT DEBERARDINE ABBOTT LABORATORIES 100 ABBOTT PARK ROAD DEPT. 377/AP6A ABBOTT PARK, IL 60064-6008			EXAMINER WHITE, EVERETT NMN	
			ART UNIT	PAPER NUMBER
			1623	
DATE MAILED: 10/13/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/501,174

Applicant(s)

STRUSZCZYK ET AL.

Examiner

Everett White

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/09/2005</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Struszczyk et al (WO 91/00298).

Applicants claim a method for deproteinizing chitosan, comprising the steps of: (a) reacting an acidic solution of chitosan, said chitosan containing proteins ≥ 0.001 wt%, with an aqueous base to precipitate microcrystalline chitosan; and (b) separating said precipitated microcrystalline chitosan from dissolved proteins to produce a microcrystalline chitosan having a protein content < 10 ppm. Additional limitations in the dependent claims include a method wherein said acidic solution of chitosan comprises an acid selected from the group consisting of hydrochloric acid, acetic acid and lactic acid; a method wherein said aqueous base is selected from the group consisting of sodium hydroxide, potassium hydroxide, sodium carbonate, and potassium carbonate; a method wherein said separating step is carried out using a method selected from the group consisting of filtration, ultrafiltration, sedimentation and centrifugation.

The Struszczyk et al publication discloses a method for continuous manufacture of microcrystalline chitosan by precipitation of chitosan from an aqueous solution in organic acid such as acetic acid, wherein the chitosan aqueous acid solution is introduced into a reactor together with an alkaline metal hydroxide solution. The microcrystalline chitosan dispersion produced is collected in a compensation tank and is continuously purified using a method that may be selected as ultrafiltration (see abstract). See example 1 wherein acetic acid and sodium hydroxide are used as the reactants. The method of manufacturing microcrystalline chitosan disclosed in the

Art Unit: 1623

Struszczyk et al publication anticipates the instantly claimed method of deproteinizing chitosan in view of the use of analogous chitosan starting material, the acetic acid and sodium hydroxide as the reactants, and ultrafiltration as the purifying method.

3. Claim 7 is rejected under 35 U.S.C. 102(b) as being anticipated by Struszczyk et al (WO 91/00298).

Applicants claim a composition of matter, comprising a chitosan in the form of a product-by-process claim.

The Struszczyk et al publication discloses microcrystalline chitosan which anticipates the instantly claimed product of claim 7. Applicants are reminded that the office considers product-by-process claims as product claims. The process limitations of this claim have not been considered since process limitations cannot impart patentability to a product that is not patentably distinguished over the prior art. *In re Thorpe et al.* (CAFC 1985), supra; *In re Dike* (CCPA 1968) 394 F2d 584, 157 USPQ 581; *Tri-Wall Containers, Inc. v. United States et al.* (Ct Cls 1969) 408 F2d 748, 161 USPQ 116; *In re Brown et al.* (CCPA 1972) 450 F2d 531, 173 USPQ 685; *Ex parte Edwards et al.* (BPAI 1986) 231 USPQ 981.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Struszczyk et al (WO 91/00298).

Applicants claim a method for deproteinizing chitosan, comprising the steps of: (a) reacting an acidic solution of chitosan, said chitosan containing proteins ≥ 0.001 wt%, with an aqueous base to precipitate microcrystalline chitosan; and (b) separating said precipitated microcrystalline chitosan from dissolved proteins to produce a microcrystalline chitosan having a protein content < 10 ppm. Additional limitations in the dependent claims include a method wherein said acidic solution of chitosan comprises an acid selected from the group consisting of hydrochloric acid, acetic acid and lactic acid; a method wherein said aqueous base is selected from the group consisting of sodium hydroxide, potassium hydroxide, sodium carbonate, and potassium carbonate; a method wherein said separating step is carried out using a method selected from the group consisting of filtration, ultrafiltration, sedimentation and centrifugation; a method wherein said reacting step is carried out at $6.0 \leq \text{pH} \leq 6.5$.

The Struszczyk et al publication discloses a method for continuous manufacture of microcrystalline chitosan by precipitation of chitosan from an aqueous solution in organic acid such as acetic acid, wherein the chitosan aqueous acid solution is introduced into a reactor together with an alkaline metal hydroxide solution. The microcrystalline chitosan dispersion produced is collected in a compensation tank and is continuously purified using a method that may be selected as ultrafiltration (see

Art Unit: 1623

abstract). See example 1 wherein acetic acid and sodium hydroxide are used as the reactants. The method of manufacturing microcrystalline chitosan disclosed in the Struszczyk et al publication embraces the instantly claimed method of deproteinizing chitosan in view of the use of analogous chitosan starting material, the acetic acid and sodium hydroxide as the reactants, and ultrafiltration as the purifying method. The instantly claimed method of deproteinizing chitosan differs from the method of manufacturing microcrystalline chitosan in the Struszczyk et al publication by claiming the reaction of the method at $6.0 \leq \text{pH} \leq 6.5$. It is within the skill of a practitioner in this art to make adjustments to this method in order to obtained optimum operation of the claimed method. The limitation of a process with respect to ranges of pH, time and temperature does not impart patentability to a process when such values are those, which would be determined by one skilled in the art in achieving optimum operation of the process. *In re Mostovych et al.* (CCPA 1964) 339 F2d 455, 144 USPQ 38; *In re Aller et al.* (CCPA 1955) 220 F2d 454, 105 USPQ 233. One having ordinary skill in the art would have been motivated to employ the process of the prior art with the expectation of obtaining the desired product because the skilled artisan would have expected the analogous starting materials to react similarly. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of Applicants invention to adjust the pH value of the reaction medium in the method of manufacturing the microcrystalline chitosan described in the Struszczyk et al publication for optimum operation of the method in view of the similar used reactants used to carry out the methods and the resulting expectation of similar microcrystalline chitosan properties.

Summary

6. All the claims are rejected.

Examiner's Telephone Number, Fax Number, and Other Information

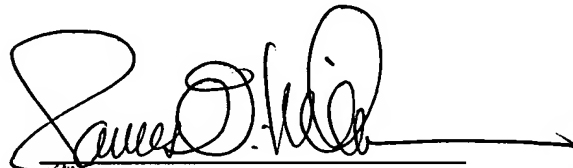
7. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit our website at www.uspto.gov and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (571) 272-0660. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reach on (571) 272-0661. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.


E. White


James O. Wilson
Supervisory Primary Examiner
Technology Center 1600